

K071352

JUN 29 2007

510(k) Summary

owner's name: Gebr. Brasseler GmbH & Co. KG

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Germany

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name of contact person: Mr. Olaf Brand

date the summary was prepared: February 2007

Establishment Registration number: 8010468

name of the device: CeraDrill

trade or proprietary name: CeraDrill

the classification name: Bone cutting instrument and accessories
(21 CFR 872.4120 Product Code DZI)

Legally marketed device to which your firm is claiming equivalence

Company:

Nobel Biocare USA, Inc.

Device:

Amorphous Diamond Coated Drill

510(k) No.:

K990846

Description of the device:

CeraDrills within the new "CeraLine" is intended for use in implantology. These are made of high efficiency ceramics featuring an excellent cutting performance. The new **CeraDrill** offers the possibility of working without any metal, thus guaranteeing a biocompatible operation. Damages, as they occur in particular when disinfecting and cleaning steel burs with inappropriate agents, are now a thing of the past. The multifunctional ceramic drills are suited for initial preparation of the implant site axis and depth. The drills feature high initial sharpness and optimal cutting efficiency, thus achieving an effective material reduction. Due to their high efficiency toothing and the distinct tip-transversing blade, the drill has very good axial drilling properties for precise cutting without the need for prior use of a centering bur. The special twist drill blade geometry ensures smooth and precise operation. Moreover, the depth markings, which are lasered on to the working part in 2 mm intervals guarantee precise and safe control of the penetration depth.

The **CeraDrill** family is available in diverse dimensions and shapes for the individual preparation on the osteotomy. The following table shows the REF numbers, diameters, penetration depth, shank types, number of cutting flutes:

Remark:

further explanations concerning the columns of the following
 table can be found in chapter 11 of this submission

Model	REF / "Bezeichnung"	ID Nr. / Ident Nr.	Descrip- tion	Diameter / SØK Kopf- durch- messer"	penetration depth / KL "Kopflänge"	Total length/ Gesamt- länge	Shank type ISO 1797	Shank type US	Cutting flutes/ Schnei- denzahl
K210L16.RA.020	K210L16.204.020	033792	CeraDrill pilot drill 2,0 L16	2,0 mm	16,0 mm	30,5 mm	204	RA	2
K210L19.RA.020	K210L19.204.020	033793	CeraDrill pilot drill 2,0 L19	2,0 mm	19,0 mm	33,5 mm	204	RA	2
K210L16.RA.028	K210L16.204.028	033794	CeraDrill pilot drill 2,8 L16	2,8 mm	16,0 mm	32,0 mm	204	RA	3
K210L19.RA.028	K210L19.204.028	033795	CeraDrill pilot drill 2,8 L19	2,8 mm	19,0 mm	35,0 mm	204	RA	3
K210L20.RASL.020	K210L20.205.020	034899	CeraDrill pilot drill 2,0 L20	2,0 mm	20,6 mm	41,0 mm	205	RASL	2
K210L20.RASL.028	K210L20.205.028	034900	CeraDrill pilot drill 2,8 L20	2,8 mm	20,84 mm	41,0 mm	205	RASL	3
K210L20.RASL.035	K210L20.205.035	035211	CeraDrill pilot drill 3,5 L20	3,5 mm	21,05 mm	41,0 mm	205	RASL	3
K210L20.RASL.042	K210L20.205.042	035212	CeraDrill pilot drill 4,2 L20	4,2 mm	21,26 mm	41,0 mm	205	RASL	3

Intended use:

CeraDrill is a ceramic pilot drill for the dental implantology made of a modern high performance ceramic. The drills are intended to be used with a handpiece.

- Indications for use

The drill is used to pre-drill into the maxilla or mandible to create an initial osteotomy for the later endosseous dental implant placement.

The drills are used with a handpiece.

- Target population

The target population for the **CeraDrill** are Patients applicable for dental treatment with endosseous implants

CeraDrill is used in the following anatomical sites: maxilla or mandible

CeraDrill is intended to be used at the Dentist

The device is an integral part of any implantological preparation.

Due to the fact that the device is intended to be used in the framework of the dental implantology the patients must be applicable for dental treatment with endosseous implants.

Summary of technological Characteristics

(compared to the predicate device)

The following table shows the technological characteristics of both devices:

Aspect	New device CeraDrill	Predicate device Amorpheus Diamond coated drill
energy used and/or delivered	The device is intended to be used in electrical powered hand pieces	same
design	two / three cutting flutes external irrigation	two / three cutting flutes internal /external irrigation
performance	Ordinary concentricity	Ordinary concentricity
corrosion	Corrosion resistive <u>Advantage:</u> <i>not leading to decolourisation while reprocessing</i>	Limited corrosion resistance for stainless steel
materials	The CeraDrill is made of $ZrO_2/Al_2O_3/Y_2O_3$ <u>Advantage:</u> - just one material - no coating - limited probability of abrasion due to inadequate bonding	stainless steel coated with diamond
Biocompatibility	According ISO 7405	same

Aspect	New device CeraDrill	Predicate device Amorpheus Diamond coated drill
Ability to be reprocessed	The CeraDrill can be used, cleaned, disinfected and sterilised according to the specifications as given in the instructions for use for at least 10 cycles. (see test report# 06m1166 in chapter 14A of this submission)	No limitation for reprocessing indicated
Mechanical stability after reprocessing	CeraDrill may be reprocessed in 100 cycles without a significant loss of mechanical stability (details see chapter 18 d)	No further explanation / information given
thermal safety	Improved thermal safety <u>Advantage:</u> <i>It was observed that the temperature rise when using ceramic burs was lower than that observed with steel burs</i> (details see chapter 18 a)	Lower thermal safety

Substantial equivalence determination

Non-clinical performance data:

The determination of substantial equivalence is based on several non-clinical tests, most of which are repeated in the body of this 510(k) submission.

This includes especially those tests showing the physical and biological characteristics. The test results can be summarised as follows:

- General technological equivalence between predicate and current device
- improved thermal safety
- improved safety concerning the risk of inadequate bonding of the coating
- the assumable lower resistive ness against bending forces during operation is negligible, since those bending force being necessary for fracture would lead to unacceptable osteotomies (=misuse)

(Details on non-clinical test can be found in chapter 18 of this submission)

Clinical performance data

The determination of substantial equivalence is not based on clinical data.

Conclusion:

The main intention of the CeraDrill is to pre-drill into the maxilla or mandible to create an initial osteotomy for the later endosseous dental implant placement. As such the CeraDrill can be concluded to be substantial equivalent to the predicate device:

Amorphous Diamond Coated Drill, Nobel Biocare, K990846

The only technical difference is the material used: whereas the predicate device is made of steel and coated with amorphous diamond the CeraDrill is made of a single material which is Zirconium oxide.

This technological difference leads to the following advantages of the CeraDrill device:

- + Metalfree preparation
- + positive Osteointgration
- + non allgergenic compared to CrNi Steal

There is no known disadvantage; the known difference in the bending strength of the materials does not have an impact in the intended use as identified in the chapter 18 of the submission.

The safety and performance data submitted in this file support a finding of substantial equivalence between the **CeraDrill** and the predicate device as specified above.

Any other information:

none



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Gebr. Brasseler GmbH & Company KG
C/O Mr. Olaf Brand
TUV Rheinland of North America, Incorporated
12 Commerce Road
Newtown, Connecticut 06470

JUN 29 2007

Re: K071352
Trade/Device Name: CeraDrill
Regulation Number: 21 CFR 872.4130
Regulation Name: Intraoral Dental Drill
Regulatory Class: I
Product Code: EIL
Dated: June 25, 2007
Received: June 27, 2007

Dear Mr. Brand:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K071352

Indications for Use

510(k) Number (if known): K071352

Device Name: CeraDrill _____

- Indications for use

The drill is used to pre-drill into the maxilla or mandible to create an initial osteotomy for the later endosseous dental implant placement.

The drills are used with a handpiece.

- specific indications:

CeraDrill is a ceramic drill for the dental implantology made of a modern high performance ceramic. The drills are intended to be used with a handpiece.

The intended use for this device is to cut into the maxilla or mandible to create an osteotomy for endosseous dental implant placement.

- clinical settings / target population:

Patients must be applicable for dental treatment with endosseous implants.

- anatomical sites:

The products are used in the framework of dental implantology for the preparation of the upper jaw (Maxilla) or the lower jaw

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Ruocco
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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